

The Real Thing Fulvic Acid Capsules

Complementary Medicine. Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

THE REAL THING FULVIC ACID CAPSULES contains carbohydrate derived fulvic acid 714 mg per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING FULVIC ACID CAPSULES contain:

	Per capsule	Per 2 capsules
Fulvic acid (as CHD-FA™ powder – carbohydrate derived)	714 mg	1 428 mg
Providing fulvic acid *	500 mg	1000 mg

* Elemental quantities calculated.

The inactive ingredients include magnesium stearate (vegetable origin), silicone dioxide, vegetable (hypromellose) capsule shell. The capsules contain sugar (Glucose 0,6%). For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING FULVIC ACID CAPSULES is a clear, hard vegetable capsule, size 00, containing a brown crystalline powder with fine off white specks.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING FULVIC ACID CAPSULES is a health supplement –

- That assists in improving uptake of minerals to support health;
- Has anti-allergy effects;
- Has antioxidant effects;
- Assists in building the immune system.

Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

Adults 18 years and older: Take 2 (two) capsules orally daily with a glass of water or consult your healthcare practitioner.

Paediatric population

THE REAL THING FULVIC ACID CAPSULES is not indicated in paediatrics. The safety in children up to age 18 years has not been established. It is not suitable for use in children.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Fulvic acid may stimulate the immune function. Advise patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others to avoid or use fulvic acid with caution.

In vitro studies show that fulvic acid can shorten prothrombin time in human plasma, increasing the risk of blood clot formation.

There is concern that high concentrations of fulvic acid (in drinking water) may contribute to the development of Kashin-Beck bone disease, particularly in areas in which selenium intake is insufficient.

4.5 Interaction with other medicines and other forms of interaction

THE REAL THING FULVIC ACID CAPSULES affecting other medicines:

Fulvic acid may decrease the effectiveness of anticoagulant and antiplatelet medicines.

Fulvic acid might decrease the effects of immunosuppressive therapy.

Fulvic acid might interfere with therapy to normalize thyroid function, therefore use cautiously in patients being treated with thyroid hormone.

4.6 Fertility, pregnancy and lactation

Advise the patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. There is insufficient reliable information available, therefore avoid using during pregnancy and breastfeeding. No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING FULVIC ACID CAPSULES may have a minor influence on the ability to drive and use machines due to possible undesirable effects.

4.8 Undesirable effects

Orally fulvic acid has been reported to cause diarrhoea, headache and sore throat in some patients.

The frequencies of these adverse reactions are not known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare practitioners are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone (021) 701-0244 or e-mail adr@therealthing.co.za

4.9 Overdose

With an overdose, side effects can be precipitated and/or be of increased severity. There is insufficient reliable information available about the toxicology of fulvic acid.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

THE REAL THING FULVIC ACID CAPSULES belongs to category D Complementary Medicines, Health Supplements, class 34.13 Other.

Fulvic acid is a group of organic, acidic polymers formed by the action of microbes on dead plant and animal material. It has shown to have anti-allergy effects, antioxidant effects, and increases the body's immune response.

5.2 Pharmacokinetic properties

Fulvic acid is well absorbed in the intestines. It is eliminated from the body within hours of ingestion.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The inactive ingredients include:

- magnesium stearate (vegetable origin)
- silicone dioxide
- vegetable (hypromellose) capsule shell.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING FULVIC ACID CAPSULES has a shelf life of 2 years when stored in a cool, dry place at or below 25 °C.

6.4 Special precautions for storage

Store in an airtight container.

6.5 Nature and contents of container

THE REAL THING FULVIC ACID CAPSULES are packed in a 200 ml amber glass bottle with a child resistant 45 mm polyethylene black screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 60 capsules.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

(To be allocated)

9 DATE OF FIRST AUTHORISATION

(To be allocated)

10 DATE OF REVISION OF THE TEXT

This is the first edition.